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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,708	06/12/2001	Se-Jin Lee	JHU1320-4	7387

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EXAMINER

ROMEO, DAVID S

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 08/11/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/880,708

Applicant(s)

LEE ET AL.

Examiner

David S Romeo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-14 is/are pending in the application.
- 4a) Of the above claim(s) 9,10,13 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-8,11 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 2-14 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The amendment filed May 30, 2003 (Paper No. 12) has been entered. Claims 2-14 are pending. Claims 9, 10, 13, 14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

Claim Rejections - 35 USC § 112

Claims 2-8, 11, 12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of detecting GDF-5 comprising the amino acid sequence shown in figure 2, does not reasonably provide enablement for a method of detecting a cell proliferative disorder by detecting GDF5.

Applicant argues that the claims have been further amended to specify that the claimed methods are directed to detecting a cell proliferative disorder associated with GDF5 by detecting an increase or decrease in the level of GDF5. Applicant's arguments have been fully considered but they are not persuasive. The specification lacks guidance for, and working examples of, GDF5 associated cell proliferative disorders. Given this lack of guidance and working examples, the skilled artisan is left to an undue amount of extensive experimentation involving extensive testing of any and/or all disorders and is left to determine if any and/or all of such disorders are GDF5 associated. To practice the claimed invention in a manner consistent with the breadth of the claims would not require just a repetition of work that is described in the present application but a substantial inventive contribution on the part of a skilled practitioner which would involve the determination of those disorders that could be reasonably classified as GDF5 associated. It is

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this additional characterization, which is not provided for in the present specification, of that single disclosed, naturally occurring GDF5 protein and the disorders with which it is associated that is required in order to obtain the information needed to permit one to practice the claimed invention that constitutes undue experimentation. The skilled artisan is left to an undue amount of unduly extensive, random, trial and error experimentation in order to determine how to achieve such detection.

Applicant argues that the specification discloses that GDF5 is expressed in adult uterine tissue in adult mice and in uterine tissue and the skeletal system in embryos, that it is known in the art that GDF polypeptides, such as GDF8, have an effect on the tissue in which they are expressed, and the skilled artisan reasonably would have known that GDF5 effects the growth and differentiation of adult uterine tissue and uterine and skeletal embryonic tissue and therefore can be associated with a cell proliferative disorder. Applicant's arguments have been fully considered but they are not persuasive. The claims are directed to or encompass detecting a "GDF-5 associated cell proliferative disorder." However, the specification lacks guidance for, and working examples of, GDF5 associated cell proliferative disorders. Given this lack of guidance and working examples, the skilled artisan is left to an undue amount of unduly extensive, random, and trial and error experimentation, as discussed above. Given this lack of guidance and working examples, the skilled artisan would not know if a particular "increased or decreased level of binding" is in fact indicative of a "GDF-5 associated cell proliferative disorder." Although the present specification indicates that GDF5 is expressed in adult uterine tissue in adult mice, no information is provided concerning GDF5's involvement in a cell

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proliferative disorder or whether an increase or a decrease in GDF5 is associated with a particular cell proliferative disorder.

Claims 2-8, 11, 12 are rejected under 35 U.S.C. 112, second paragraph, as being

5 indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 2-8, 11, 12 are indefinite because they recite the term "GDF5". Applicant argues that claim 2 has been amended to indicate that the term "GDF-5" refers to "growth differentiation factor-5" and that the antibody "specifically binds to a GDF-5 polypeptide having an amino acid sequence as set forth in SEQ ID NO: 10 or SEQ ID NO: 13."

10 Applicant's arguments have been fully considered but they are not persuasive. Although the claims, as amended, make it clear that the antibody binds a GDF-5 having an amino acid sequence as set forth in SEQ ID NO: 10 or SEQ ID NO: 13, the claims also recite "a growth differentiation factor-5 ... cell proliferative disorder," "GDF-5 specific antibody," "GDF-5 associated disorder," and "GDF-5 associated cell proliferative disorder," and the GDF-5 in the

15 terms "a growth differentiation factor-5 ... cell proliferative disorder," "GDF-5 specific antibody," "GDF-5 associated disorder," and "GDF-5 associated cell proliferative disorder," is not limited to "having an amino acid sequence as set forth in SEQ ID NO: 10 or SEQ ID NO: 13."

20 Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 14 is indefinite because it recites the term "modified cellulose". Applicant

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argues that one skilled in the art would know the metes and bounds of the term, and that one skilled in the art would know many examples of modified cellulose products, as evidenced by exhibits A-C. Applicant's arguments have been fully considered but they are not persuasive.

There is nothing in the specification, prosecution history, or prior art that provides any indication

5 as to what modification is intended by the term "modified" or that the nature and extent of modification is limited by exhibits A-C. The metes and bounds are not clearly set forth.

New Formal Matters, Objections, and/or Rejections:

Claim Rejections - 35 USC § 112

10 Claims 2-8, 11, 12, 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 2-8, 11, 12, 14 are indefinite because they recite the term "normal cell". Because the instant specification does not identify that material element or combination of elements which is unique to, and, therefore, definitive of "normal cell" an artisan
15 cannot determine what additional or material limitations are placed upon a claim by the presence of this element. The term "normal" in claim 2 is a relative term which renders the claim indefinite. The term "normal" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention.

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Conclusion

No claims are allowable.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

5 A shortened statutory period for reply to this final action is set to expire **THREE**
MONTHS from the mailing date of this action. In the event a first reply is filed within **TWO**
MONTHS of the mailing date of this final action and the advisory action is not mailed until after
the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period
will expire on the date the advisory action is mailed, and any extension fee pursuant to 37
10 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,
however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this
final action.

15 ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO
DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH
FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE
REACHED ON (703) 308-4623.

20 IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO
THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

BEFORE FINAL (703) 872-9306


AFTER FINAL (703) 872-9307

IN ADDITION TO THE OFFICIAL RIGHTFAX NUMBERS ABOVE, THE TC 1600 FAX CENTER HAS THE FOLLOWING OFFICIAL FAX
NUMBERS: (703) 305-3592, (703) 308-4242 AND (703) 305-3014.

25 CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL
OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

30 ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED
TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

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DAVID ROMEO
PRIMARY EXAMINER
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